REMARKS

Claims 16-22 and 25-30 are pending in the instant application. Claims 23 and 24 have been previously cancelled. Applicants have amended claim 25. No new matter has been added by these amendments.

The Office Action has asserted objections against claims 25-27, has rejected all pending claims under 35 U.S.C. § 103, and has asserted a provisional non-statutory double patenting rejection against all pending claims. In view of the amendments and remarks, Applicants respectfully request that the rejections be reconsidered and withdrawn.

OBJECTION TO CLAIMS 25-27

Claims 25-27 have been objected to under 37 C.F.R. § 1.75(c) as being in improper dependent form. Particularly, the Office Action asserts that these claims do not further limit claim 16 because they only further limit the preamble.

Applicants respectfully traverse this objection because, in this case, the preamble, when read in the context of the entire claim, recites a limitation. "The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002)" (MPEP § 2111.02).

> "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

(MPEP § 2111.02).

In this case, claim 16 recites "a gauge for use in a ***surgical procedure*** to determine ***a first angle*** in a first plane and a second angle in ***a second plane***, said gauge comprising ..." (emphasis added). Surgical procedure is necessary to give life, meaning and vitality to the remainder of the claim because it limits the recited gauge to those used in surgical procedures, as opposed to any other type of gauge. Amended claim 25, which

depends from claim 16, recites that "said surgical procedure is hip replacement." Since claim 25 further defines "surgical procedure", and since "surgical procedure" is a limitation, claim 25 is a proper dependent claim.

Likewise, claims 26 and 27 further the first and second angle limitations. The first and second angle limitations breathe life, meaning and vitality to the plumb bob. Moreover, claim 16 recites "said first angle" and "said second angle" within the body of the claim. Accordingly, claims 26 and 27 are likewise proper dependent claims.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 16-22 and 25-28 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,122,145 to Fishbane (hereinafter "Fishbane") in view of U.S. Patent No. 2,385,424 to Shue *et al.* (hereinafter "Shue").

The invention, as recited in amended claim 16, is directed to a gauge for use in a surgical procedure to determine a first angle in a first plane and a second angle in a second plane. The gauge has a body, and a connector is disposed on the body. The connector is used to mount the gauge onto a prosthetic component and a predefined site of a patient simultaneously. This allows correlation between the predefined site of said patient and positioning of the prosthetic component.

Fishbane is directed to a measuring device that provides a leveling means (Fishbane at col. 1, lines 19-25). The leveling means is to ensure the proper positioning of the femur. Fishbane's leveling means is described as a small bubble level 10 (Fishbane at col. 2, lines 32-34). It is positioned on the top surface 50 of an interconnecting measuring member 8 (Fishbane at col. 3, lines 45-48). In practicing Fishbane's invention, "[t]he leg of the patient is moved, thereby moving the femur to center the bubble of the leveling device 10" (Fishbane at col. 3, lines 48-50). Thus, Fishbane's invention only ensures that the femur is level. The bubble is not capable of measuring the recited first and second angles because Fishbane does not teach a connector.

On page 2, the Office Action contends that Fishbane's acetabular guide 4 and femoral guide 6 are equivalent to the recited connector. The acetabular guide 4 comprises a bar 12 having a cylindrical pin guide 14 fixed at each end of the bar 12 (Fishbane at col. 2,

lines 12-13). The pin guides 14 cooperate with the Steinmann pins 40 set in the ilium 42 above the acetabulum 43. The Steinmann pins 40 and the ilium 42 are not a prosthetic component.

Fishbane's femoral guide 6 likewise does not mount a gauge onto a prosthetic component. As the name implies, it mounts to a femur, particularly a Steinmann pin 44 set in the femur 46 (Fishbane at col. 3, lines 61-64).

The Office Action contends that Shue discloses a gauge wherein the level is a plumb bob mounted on a body and that the plumb bob hands under the influence of gravity (Office Action at page 3).

As part of a *prima facie* case, an examiner must ascertain the differences between the prior art and the recited invention, and evaluate whether the combination reasonably leads to the recited invention. See MPEP §§ 2141 and 2141.02. In this case, the combination does not lead to the recited invention. Fishbane is directed to leveling a femur. The device, as depicted in Fishbane Fig. 3, sits on top of pins implanted in the bone. Replacing Fishbane's bubble level with Shue's plumb bob level would still only allow one to level a femur because Fishbane does not teach a connector disposed on a body for mounting of a gauge to a prosthetic component and a predefined site of a patient to allow correlation between the predefined site of the patient and positioning of the prosthetic component. It is only directed to leveling a femur.

Accordingly, the combination of Fishbane and Shue does not teach or suggest the recited connector, and the combination does not result in the recited gauge. For these reasons, Applicants respectfully request that the rejections asserted against claims 16-22 and 25-28 be reconsidered and withdrawn.

Claims 29 and 30 have been rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,314,432 to Paul (hereinafter "Paul") in view of U.S. Patent No. 1,495,629 to Arthur (hereinafter "Arthur"). However, these references do not teach or suggest the recited connector.

Claim 29 is directed to a gauge for use in a surgical procedure to determine a first angle in a first plane and a second angle in a second plane. The gauge comprises a

body, a first plumb bob is mounted to the body so as to hang under the influence of a local gravitational field. A second plumb bob is mounted to the body so as to hang under the influence of a local gravitational field. A connector is disposed on the body for connection of the gauge to a prosthetic component of a predefined site of a patient.

On pages 4-5, the Office Action contends that Paul discloses a gauge 10 having a first level 26, a second level 27, and a connector 36. According to Paul, part 36 is a contact adhesive (Paul at col. 3, lines 60-61). Specifically, Paul states that "[i]n FIG. 4 peel strip 35 can be separated from contact adhesive 36 so that base plate 20 can be adhesively secured to skin surface when stereotactic device 10 is positioned over the spinal area of a prone patient."

On page 5, the Office Action contends that by replacing Paul's first and second levels with two copies of Arthur's plumb bob 19, the recited invention is reached. However, this combination lacks the recited connector. Paul's contact adhesive 36 adheres to the skin. Therefore, it does not connect to a prosthetic component.

For this reason, the combination of Paul and Arthur does not teach or suggest the invention as recited in claim 29, or claim 30, which depends from claim 29.

PROVISIONAL DOUBLE PATENT REJECTION

Claims 16-22 and 25-30 have been provisionally rejected as purportedly unpatentable over claims 161-193 in co-pending U.S. App. No. 10/494,085 ("the co-pending '085 application") on the grounds of non-statutory double patenting. As of the date of this Amendment, claims 161-193 in the co-pending '085 Application have not been allowed. As such, Applicants are not required to address this provisional rejection at this time, and will address this provisional rejection if and when claims 161-193 in co-pending '085 Application are allowed.

On page 6, the Office Action contends that the double patenting rejection is proper and should be maintained. Applicants have not previously requested that the provisional double patenting rejection be withdrawn. The Applicants have only stated that they are not required to substantively address this rejection until at least one of the ms 161-193 in the co-pending '085 application is allowed and a patent is issued.

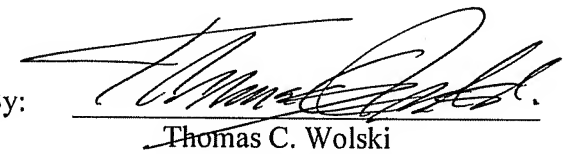
CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that claims 16-22 and 25-30 in the instant application are novel and patentable over the prior art, and are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections, and allowance of these claims are respectfully requested.

Should the Examiner have any questions or concerns, the Examiner is invited to contact Applicants' undersigned attorney by telephone at 412-471-8815.

Respectfully submitted,

THE WEBB LAW FIRM

By: 

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